Update on HIV Rapid Tests

Carol Fridlund

Bernard M Branson, MD

Centers for Disease Control and Prevention

CDC Efforts and the Availability of Rapid Tests

- *Encourage manufacturers to commercialize rapid tests in the United States.*
- *Conduct clinical trials to establish test performance in settings of intended use.*
- *Evaluate use of specific combinations of rapid tests to increase predictive value.*
- *“Treatment IDE” for expanded access to rapid tests*

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Interpreting Rapid Test Results

For a laboratory test:

Sensitivity: Probability test=positive if patient=positive

Specificity: Probability test=negative if patient=negative

Predictive value:

Probability patient=positive if test=positive

Probability patient=negative if test=negative

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Example: Test 1,000 persons

Test Specificity = 99.6% *(4/1000)*

HIV prevalence = 10%

True positive: 100 False positive: 4

Positive predictive value: 100/104 = 96%

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Example: Test 1,000 persons

Test Specificity = 99.6% *(4/1000)*

HIV prevalence = 10%

True positive: 100 False positive: 4

Positive predictive value: 100/104 = 96%

HIV prevalence = 0.4%

True positive: 4 False positive: 4

Positive predictive value: 4/8 = 50%

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Predictive Value: Single Screening Test

Test Specificity 99.6%

HIV Prevalence	Predictive Value Positive
10%	96%
5%	91%
2%	80%
3%	86%
1%	67%
0.5%	50%
0.3%	38%
0.1%	18%

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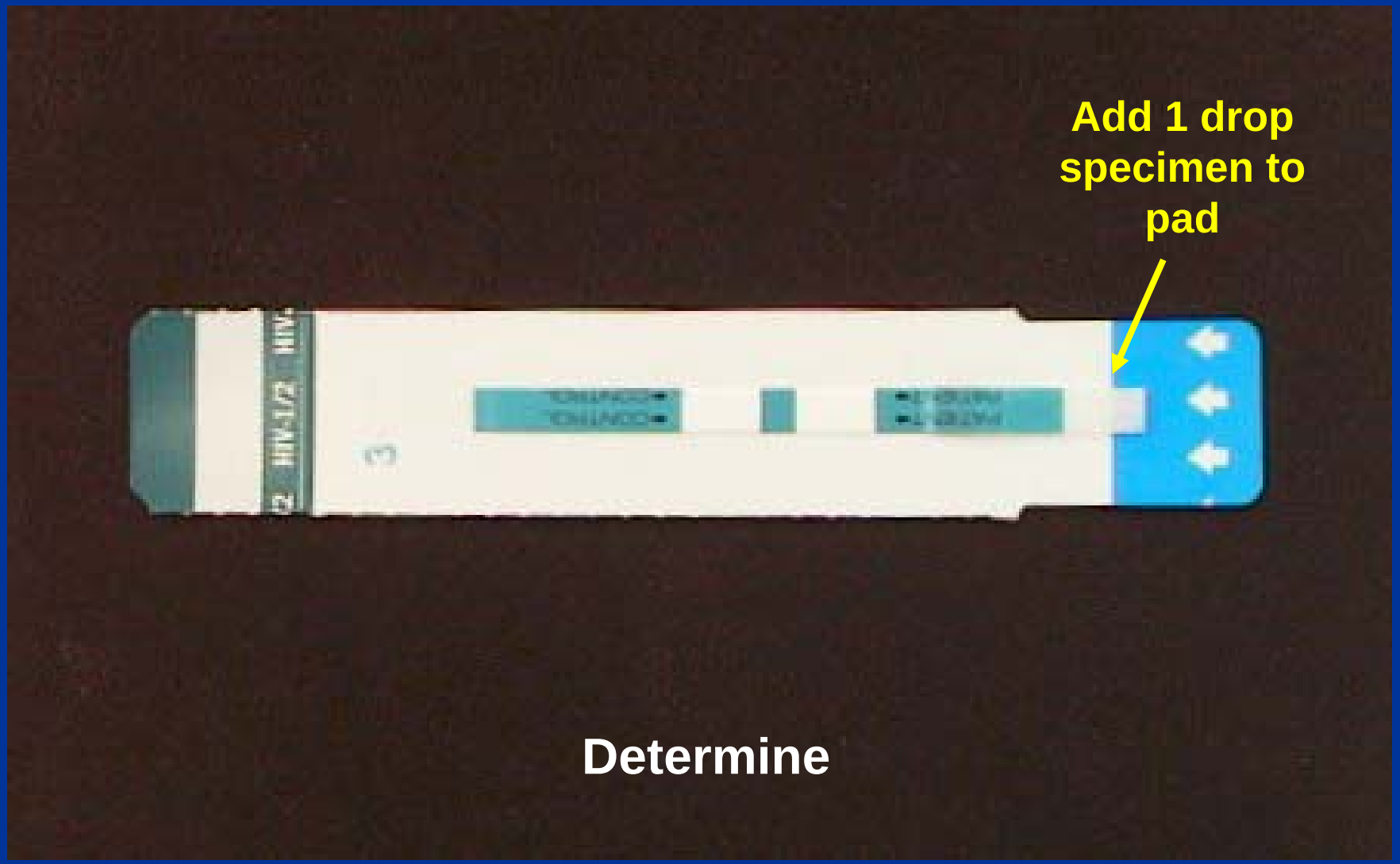

Add serum or whole blood & buffer

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Read test results in 15 minutes

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OraQuick: Whole blood, serum, oral fluid

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OraQuick

Oral fluid specimens can reduce hazards, facilitate testing in field settings

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Add 5 µl specimen to vial; insert paddle

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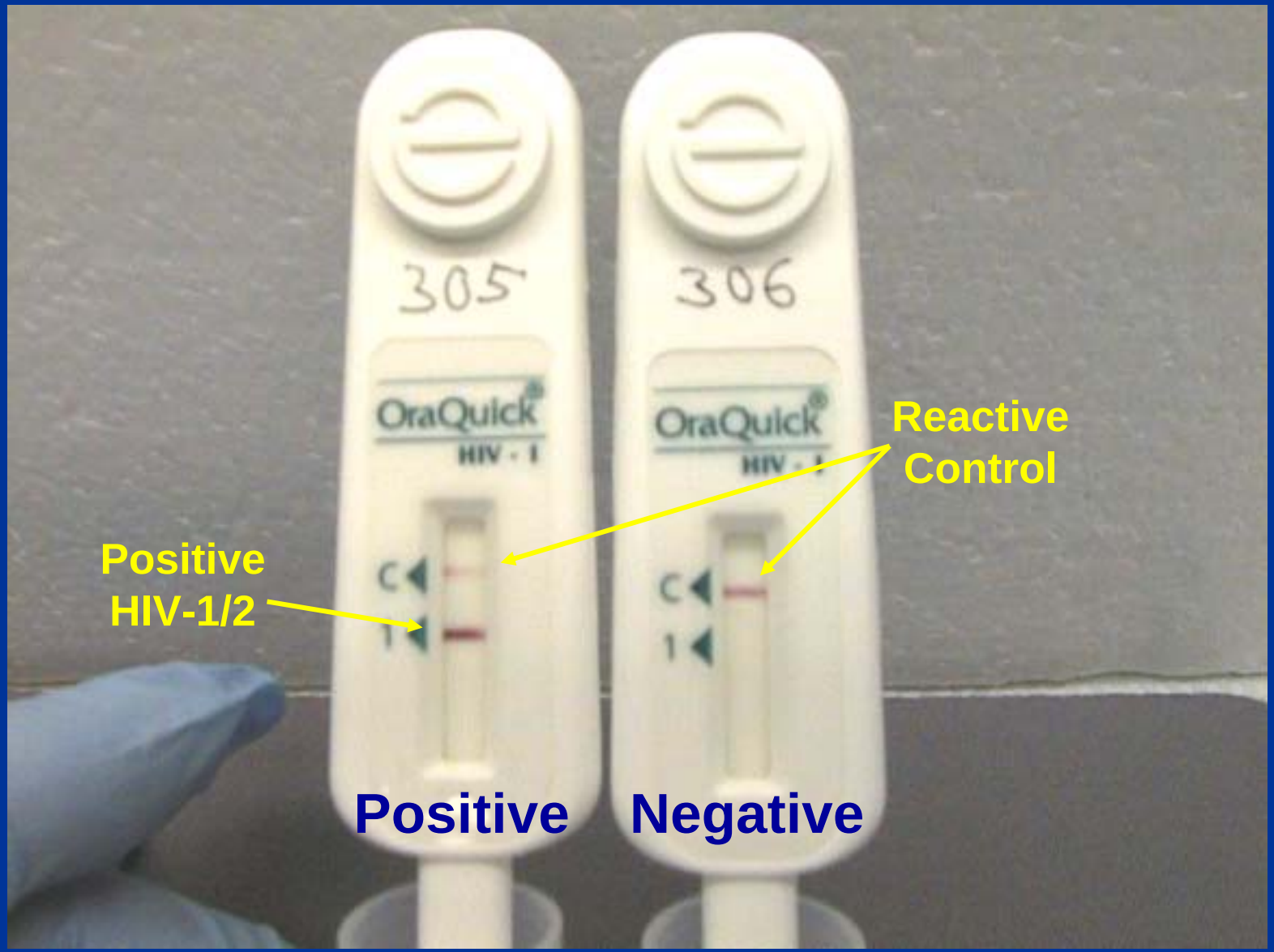

Read results in 20 minutes

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Multispot HIV-1/HIV-2

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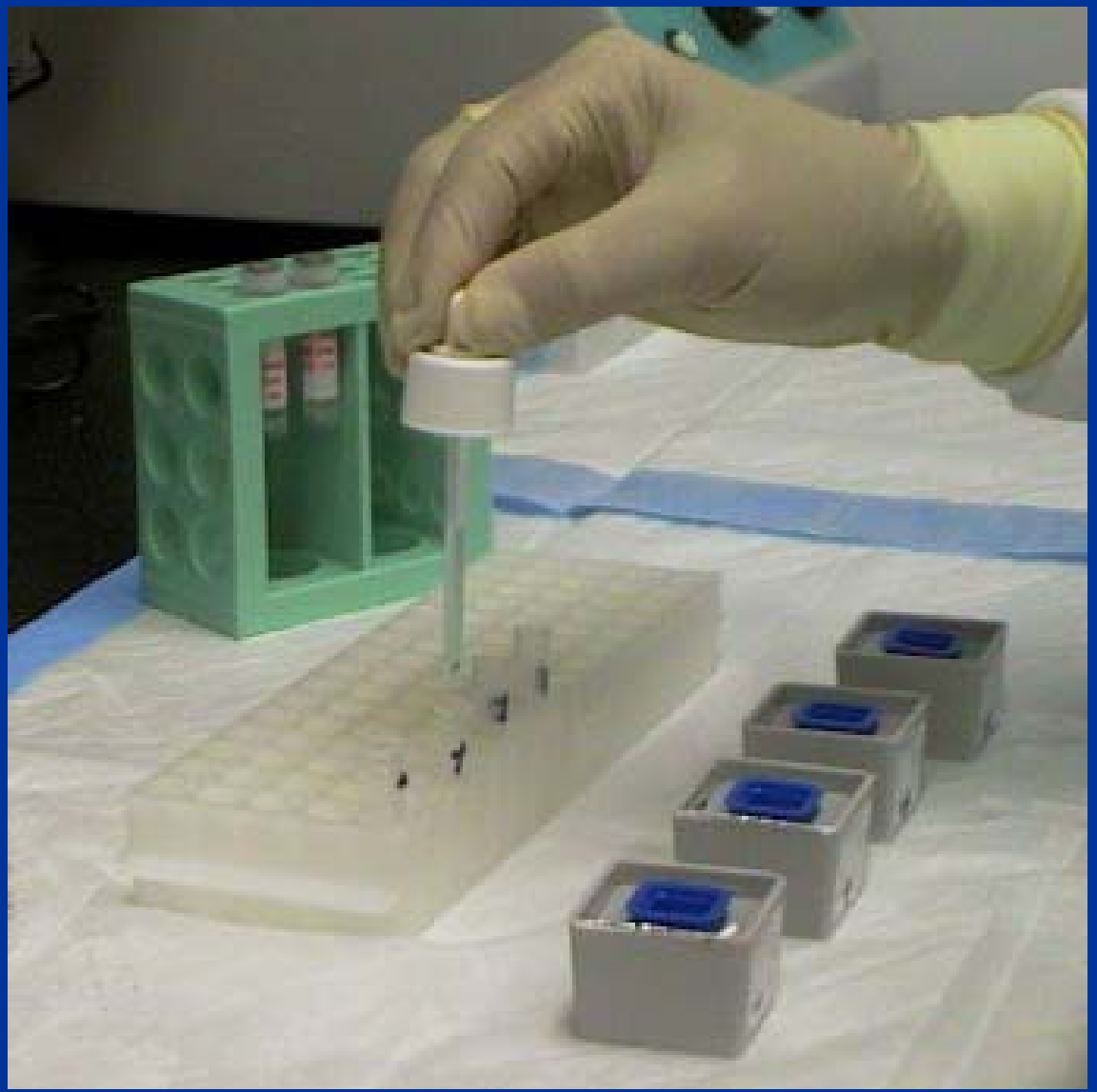

Dilution of plasma or serum

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Several reagent & wash steps

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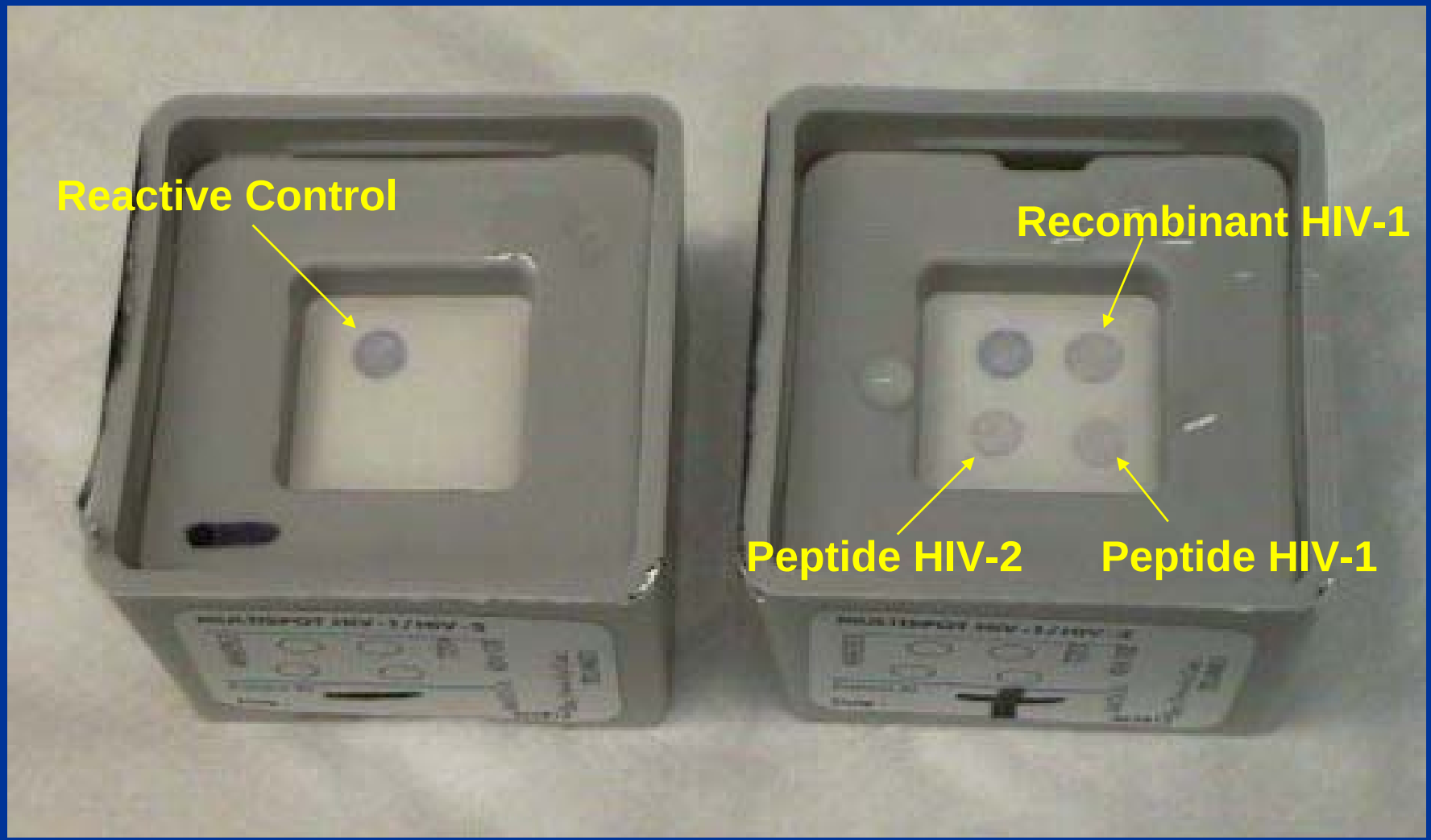

Negative

HIV-1 & HIV-2 Positive

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Rapid Test Performance: Plasma

	False Negative	Sensitivity	False Positive	Specificity
Determine	0	100%	0	100%
Hemastrip	4	98.5%	0	100%
MedMira	10	96.7%	7	98.5%
MultiSpot	0	100%	6	98.7%
OraQuick	0	100%	1	99.6%
Unigold	2	99.1%	1	99.8%
SUDS	1	99.7%	1	99.8%

341 HIV+, 466 HIV- persons

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Rapid Test Performance: Prospective Study

	False Negative	Sensitivity	False Positive	Specificity
Determine	0/62	100%	2/1152	100%
MedMira	3/61	95.1%	15/1098	98.6%
MultiSpot	0/27	100%	0/493	100%
OraQuick	0/62	100%	3/11431	99.8%
OraQuick Oral	0/61	100%	4/1089	99.6%
Unigold	4/45	91.1%	2/915	99.8%
SUDS	1/62	98.4%	6/1149	99.5%

1214 Clients at Testing Site /STD Clinic

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Treatment IDE

- *"Investigational Device Exemption" from FDA*
- *Allows use of investigational tests in certain populations and situations*
- *Requires investigator, protocol, IRB approval*
- *Manufacturer: single test*
- *CDC: plans several tests in combination*

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Next Steps

- Evaluate combinations of rapid tests for screening and diagnosis
- Determine eligibility for CLIA waiver
- Repeat evaluations with new crop of tests

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